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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P 0020	5717
42016 7590 07/28/2008 KENSEY NASH CORPORATION 735 PENNSYLVANIA DRIVE EXTON, PA 19341				
EXAMINER SILVERMAN, ERIC E				
ART UNIT 1618		PAPER NUMBER		
MAIL DATE 07/28/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/010,304

Applicant(s)

RINGEISEN, TIMOTHY

Examiner

Eric E. Silverman

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10, 14, 28 and 33-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10, 14, 28, 33-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 6-10, 14, 28, 33-52 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-10, 14, 28, 33-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. An invention is not enabled if it cannot be practiced without undue experimentation. Undue experimentation is considered in view of the factors enumerated in MPEP 2164.01. All of these factors have been considered, and the most relevant are discussed below.

1. Breadth of the claims/nature of the invention

The invention includes many independent claims, all of which have the common features of being method claims wherein a polymer is dissolved in a solvent to form a solution and adding a second liquid thereto so that the entire volume of solution and second liquid agent coalesce into a gel at the end of the addition. The claims are understood to require that the resulting product has no discernable liquid phase, and that all of the added second liquid is incorporated into the gel. The second liquid is

called a "swelling agent", "second solvent", or "added liquid" in the various claims, but serving the same function in all. For the purposes of this discussion, the term second liquid will be used to include all of the above.

2. State of prior art/level of predictability in the prior art

The prior art of record is similar to the claims, with the only relevant difference being that when the second liquid is added (or the polymer solution is added to the second liquid) the result is a two-phase system wherein the entire volume of the second liquid is not incorporated into the gel. For example, in Dunn (of record), there are 10 examples using different polymers, none of which results in the swelling of the entire volume of both the polymer solution and the second liquid. Einstman has similar teachings. As such, the prior art is counter-predictive, and strongly indicates that the process of the instant claims will not result in a system where the entire volume of both the polymer solvent and second liquid are incorporated into the gel.

3. The direction provided by the inventor and working examples

The inventor provides only minimal guidance. The specification indicates how to determine the identity of a polymer solvent and how to determine the identity of a second liquid. But the specification does not actually show how the mixing of these two (polymer in polymer solvent and second liquid) can give the claimed result. Indeed, the working examples, which use only one polymer, an aromatic polyurethane, and only one polymer solvent, THF, do not even show gel formation. The working examples only specify that for the aromatic polyurethane dissolved in THF, when any of nine appropriate second liquids (as determined by methods disclosed in the specification)

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are added, the result is that the solution increases in viscosity. An increase in viscosity does not actually mean gel formation. As such, the artisan reading the instant specification has not been informed of any method that actually leads to gellation of the entire volume of the polymer solution and the second liquid, as claimed.

Nor does the specification take into account that the second liquid need not be soluble in the polymer solvent. In this case, there is an additional degree of unpredictability, because it appears unlikely that two liquids that do not form a homogeneous mixture would be co-incorporated in their entirety in a gel.

4. Quantity of experimentation needed

Here, the quantity of experimentation needed is undue. While the specification provides some information about how to select a polymer solvent and a second liquid, the record in its entirety indicates that there is no predictability as to whether any given combination of polymer solvent, polymer, and second liquid will in fact form a gel without leaving any solvent or second liquid unincorporated in the gel. Indeed, even in the working example, it is not clear that all of the combinations that Applicants identify as suitable for the method will actually work. Thus, the artisan seeking to practice the claimed method must start from scratch in determining what combinations of polymer, polymer solvent and second liquid will form a gel, and then determine what conditions, if any, are suitable for making a gel that incorporates all of the polymer solvent and second liquid.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim requires "avoiding the use of" water or ethanol. It is not clear what would constitute the "use" of water or ethanol in this claim. Does the "use" mean adding this to the solvent or second liquid in the process of claim 6, soaking the formed gel in water or ethanol to "leach" the solvents, or something else?

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman
Art Unit 1618